CLAIMS

- 1. An osteoclastogenesis inhibitory factor protein comprising the following properties:
 - (a) molecular weights as determined by SDS-polyacrylamide gel electrophoresis (SDS-PAGE) of approximately 60 kD under reducing conditions, and approximately 60 kD and 120 kD under non-reducing conditions;
 - (b) high affinity to cation-exchange resins and heparin derivatized substrates;
 - (c) inhibition activity: inhibits osteoclast differentiation or maturation, wherein the inhibition activity is decreased by heating at about 70°C for about 10 min. or at about 56°C for about 30 min., and wherein said activity is lost by heating at about 90°C for about 10 min.; and
 - (d) internal amino acid sequences substantially in accordance with Seq. ID Nos. 1, 2 and 3.
 - 2. The protein of claim 1 comprising the N-terminal amino acid sequences provided in Seq. ID No. 7.
 - 3. The protein of claim which is derived from human fibroblasts.
 - 4. A method of producing an osteoclastogenesis inhibitory factor protein comprising the steps of

cultivating human fibroblast cells;

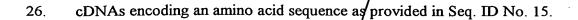
forming a lysate of said fibroblast cells; and

separating said factor from said fibroblast cell lysate by a combination of ion-exchange, affinity, and reverse phase chromatography.

The method of claim 4 further comprising the step of cultivating the human fibroblasts on alumina ceramic pieces.

- 6. A protein comprising an amino acid sequence as provided in \$eq. ID No. 4.
- 7. cDNAs encoding an amino acid sequence as provided in Seq. ID No. 4.
- 8. cDNA comprising a nucleotide sequence as provided in Seq. ID No. 6.
- 9. cDNAs that hybridize to a cDNA as provided in Seq./ID No. 6 under moderately stringent conditions.
- 10. A protein expressed from cDNA encoding an amino acid sequence as provided in Seq. ID No. 4.
- 11. A protein having a biological activity to inhibit osteoclast differentiation or maturation, said protein having an amino acid sequence expressed from a cDNA sharing at least about 80% sequence identity with the amino acid sequence provided in Seq. ID No. 4.
- 12. A recombinant protein which inhibits of teoclast differentiation or maturation expressed from a cDNA encoding an amino acid sequence as provided in Seq. ID No. 4; said protein comprising the following properties:
 - (a) molecular weights as determined by SDS-polyacrylamide gel electrophoresis (SDS-PAGE) of approximately 60 kD under reducing conditions, and approximately 60 kD and 120 kD under non-reducing conditions;
 - (b) high affinity to cation exchange resins and heparin derivatized substrates;
 - (c) inhibitory activity: inhibits osteoclast differentiation or maturation, wherein said activity is decreased by heating at about 70°C for about 10 min. or at about 56°C for about 30 min., and wherein said activity is lost by heating at about 90°C for about 10 min.; and
 - (d) an internal amino acid sequence as provided in Seq. ID Nos. 1-3.

- 13. The protein of claim 10 produced by gene engineering using mammalian cells as host cells.
- 14. The protein of claim 13 wherein said mammalian cells are 293/EBNA cells or CHO cells.
- 15. A cDNA comprising a nucleotide sequence as provided in Seq. ID No. 8.
- 16. A protein encoded by a cDNA having a nucleotide sequence as provided in Seq. ID No. 8.
- 17. cDNAs encoding amino acid sequence as provided in Seq. ID No. 9.
- 18. A cDNA comprising a nucleotide sequence as provided in Seq. ID No. 10.
- 19. A protein encoded by a cDNA comprising a nucleotide sequence as provided in Seq. ID No. 10.
- 20. cDNAs encoding an amino acid sequence/as provided in Seq. ID No. 11.
- 21. A cDNA comprising a nucleotide sequence as provided in Seq. ID No. 12.
- 22. A protein encoded by a cDNA having a nucleotide sequence as provided in Seq. ID No. 12.
- 23. cDNAs encoding an amino acid sequence as provided in Seq. ID No. 13.
- 24. A cDNA comprising a nucleotide sequence as provided in Seq. ID No. 14.
- 25. A protein encoded by a cDNA having a nucleotide sequence as provided in Seq. ID No. 14.



- An antibody having specific affinity to the osteoclastogenesis inhibitory factor protein of claim 1.
- 28. The antibody of claim 27 that is polyclonal.
- 29. The antibody of claim 27 that is monoclonal.
- 30. The monoclonal antibody of claim/29 comprising the following properties: a molecular weight of about 1/30,000, and of subclass IgG₁, IgG_{2a}, or IgG_{2b}.
- 31. A method for determining the concentration of an osteoclastogenesis inhibitory factor protein comprising contacting a sample suspected of containing said protein with an antibody of claim 27, 28, 29 or 30 under conditions sufficient to induce formation of protein-antibody conjugates, and detecting the amount of protein-antibody conjugates formed.

